



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,534	11/24/2003	Jack D. Burton	330651	3647

35657 7590 03/27/2007

FAEGRE & BENSON LLP  
PATENT DOCKETING  
2200 WELLS FARGO CENTER  
90 SOUTH SEVENTH STREET  
MINNEAPOLIS, MN 55402-3901

EXAMINER

DUFFY, BRADLEY

ART UNIT

PAPER NUMBER

1643

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/718,534

Applicant(s)

BURTON ET AL.

Examiner

Brad Duffy

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,8-10,12-19,22-36 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,7,11,20, 21 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/09/2007</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. The amendment filed January 5, 2007, is acknowledged and has been entered. Claims 1, 6 and 11 have been amended.
2. Claims 1-38 are pending in the application.
3. Claims 1-3, 6-7, 11, 20 and 21 are currently under prosecution.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. The following Office action contains NEW GROUNDS of rejection.

### ***Election/Restrictions***

6. After further consideration, claims directed to the invention of Group XXXIII have been rejoined with claims directed to the invention of Group V; and to that extent, the restriction and election requirement set forth in the Office action mailed August 4, 2006, has been withdrawn. Notably, Group XXXIII includes claim 37, and is drawn to a targeting moiety comprising a conjugate of an antibody specific to HLA-DR linked to the ligand-binding region of IL-13R $\alpha$ . As evidenced by, Rolling et al (FEBS Letters 393:53-56, 1996) the polypeptide subunit designated "IL4R $\alpha$ " is common to *both* the IL4 receptor and the IL13 receptor (see entire document, e.g., page 53, left column). Therefore, it appears that the alpha subunit of the IL13 receptor is identical to the alpha subunit of the IL 4 receptor, and thus the targeting moiety comprising a conjugate of an antibody linked to a ligand binding region of IL-13R $\alpha$ , wherein the antibody is specific for HLA-DR, (i.e., as is the invention of Group XXIII, claim 37) and the targeting moiety that is the elected invention (i.e., a targeting moiety comprising a conjugate of an antibody

linked to a ligand binding region of IL-4R $\alpha$ , wherein the antibody is specific to HLA-DR, are patentably indistinguishable.

### ***Information Disclosure Statement***

7. The reference cited in the information disclosure statement filed on January 9, 2007, has been considered.

### ***Grounds of Objection and Rejection Withdrawn***

8. Unless specifically reiterated below, Applicant's amendment and/or arguments filed January 9, 2007, have obviated or rendered moot the grounds of objection and rejection set forth in the previous Office action mailed October 2, 2006.

### ***Ground of Objection Maintained***

9. The objection to claims 1-3, 7, 20 and 21 as being drawn to non-elected inventions is maintained.

At page 8 of the amendment filed January 9, 2007, Applicant has traversed this ground of rejection.

Applicant's argument has been carefully considered but not found persuasive for the following reasons:

While Applicant has argued that interleukin-2 receptor  $\alpha$  (IL-2R  $\alpha$ ), interleukin-4 receptor  $\alpha$  (IL-4R  $\alpha$ ), and interleukin-15 receptor  $\alpha$  (IL-15R  $\alpha$ ) are part of the Markush-type group claim and therefore should be considered species of invention, it is noted that in order to be considered a proper Markush group that the elements recited must share unity of invention. Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility. See MPEP 803.02. Notably, in this case, each receptor comprises a distinct amino acid sequence and binds a structurally and functionally

distinct ligand. Therefore, the listed receptors do not share a common utility and therefore cannot share substantial structural features essential to a common utility.

Applicant has further argued on page 9 of the amendment that claim 1 in a linking claim. In this case, claim 1 does not link inventions that are drawn to interleukin-2 receptor  $\alpha$  (IL-2R  $\alpha$ ) and interleukin-15 receptor  $\alpha$  (IL-15R  $\alpha$ ) with inventions drawn to interleukin-4 receptor  $\alpha$  (IL-4R  $\alpha$ ) because these receptors do not share unity of invention. Instead claim 1 links inventions drawn to targeting moieties comprising interleukin-4 receptor  $\alpha$  (IL-4R  $\alpha$ ) and an antibody that is specific for a cell marker specific to a targeted cell (e.g., claim 1 links the instantly elected group, which is drawn to a targeting moiety comprising a conjugate of an antibody specific for HLA-DR linked to interleukin-4 receptor  $\alpha$  (IL-4R  $\alpha$ ) with the group drawn to a targeting moiety comprising a conjugate of an antibody specific for CEA linked to interleukin-4 receptor  $\alpha$  (IL-4R  $\alpha$ ), which was set forth as Group II in the restriction requirement mailed August 4, 2006. Since claim 1 links antibodies specific for a cell marker specific to a targeted cell, the claims will be examined to the extent they read on interleukin-4 receptor  $\alpha$  (IL-4R  $\alpha$ ) conjugated to antibodies encompassed by the claims.

Therefore, since these receptors lack unity of invention and the inventions that are drawn to interleukin-2 receptor  $\alpha$  (IL-2R  $\alpha$ ) and interleukin-15 receptor  $\alpha$  (IL-15R  $\alpha$ ) are not linked to inventions comprising interleukin-4 receptor  $\alpha$  (IL-4R  $\alpha$ ), these claims remain objected to as being drawn to non-elected inventions.

### ***Response to Arguments***

10. Applicant's arguments with respect to the rejections of the claims under 35 U.S.C. §103(a) and on the grounds of nonstatutory obviousness-type double patenting for the reasons set forth in the preceding Office action have been considered but are moot in view of the following new grounds of rejection.

### ***New Grounds of Rejection***

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-3, 7, 20, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Konig et al (Immunology, 85:604-610, 1995) as evidenced by Coleman et al (Protein Expression and Purification, 32:246-251, 2003), Guyre et al (Cancer Immunol Immunother, 45:146-148, 1997) and Seipelt et al (Biochem Biophys Res Comm, 239:534-542, 1997, IDS filed 9/25/2006).

Claims 1-3 and 7 are drawn to a targeting moiety comprising a conjugate of an “antibody” specific for a cell marker on targeted cells linked to the ligand-binding region of interleukin-4 receptor  $\alpha$  (IL-4R $\alpha$ ). Claims 20 and 21 are drawn to a composition comprising such a targeting moiety and a pharmaceutically acceptable carrier.

At page 7 the specification discloses, “[w]hen the term “antibody” is used herein, all the above types of fragments are included therein”, and at page 6 the specification teaches that suitable antibody fragments include antibody fragments up to the size of a F(ab')<sub>2</sub> (i.e., inclusive of smaller antibody fragments, e.g., Fab, Fc).

For good measure, as evidenced by Coleman et al (Protein Expression and Purification, 32:246-251, 2003) antibody Fab fragments and Fc fragments of an IgG antibody are both approximately 50 kDa (see entire document, e.g., page 249, left column and Figure 3). Therefore, as an  $F(ab')_2$  fragment comprises two Fab fragments it would have an approximate molecular weight of 100 kDa. Finally, as evidenced by Guyre et al (Cancer Immunol Immunother, 45:146-148, 1997) the Fc fragment of IgG is specific for the cell marker CD64 and is used to target monocytes, macrophages and dendritic cells (see entire document, e.g., abstract and page 148, left column). Since the Fc fragment is approximately 50 kDa (i.e. smaller than an  $F(ab')_2$  fragment) and the Fc fragment targets a cell marker specific to targeted cells, the Fc fragment would reasonably be considered an antibody encompassed by the claims according to the specification.

Konig et al teach a fusion protein comprising the ligand-binding extracellular domain of IL-4R linked to an Fc antibody fragment from human IgG (see entire document, e.g., abstract and page 605, left column). Furthermore, Konig et al teach said fusion protein in various experiments (e.g., Figure 2), so Konig et al inherently teach a composition comprising the fusion protein in an aqueous solution that comprises water.

Absent a showing of any difference, the disclosed aqueous solution comprising water (i.e., a pharmaceutically acceptable carrier) is the same as the compositions to which claims 20 or 21 are directed.

As evidenced by Seipelt et al (Biochem Biophys Res Comm, 239:534-542, 1997, IDS filed 9/25/2006) the extracellular domain of IL-4 receptor is also known as IL-4R $\alpha$  (see entire document, e.g., 534, right column). Thus, Konig et al teach a "targeting moiety" comprising a covalent conjugate of IL-4R $\alpha$  and an "antibody" specific for a cell marker specific to a targeted cell (i.e., Fc fragment<sup>1</sup>).

---

<sup>1</sup> It is aptly noted that the "Fc" fragment of an antibody is capable of binding specifically to a cell marker specific to a targeted cell (e.g., the Fc binds to CD64, which is expressed at the surface of targeted cells such as monocytes, macrophages and dendritic cells).

Therefore, the fusion protein of Konig et al anticipates the subject matter to which the claims are directed.

13. Claims 1-3, 7, 20, and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Seipelt et al (Biochem Biophys Res Comm, 239:534-542, 1997, IDS filed 9/25/2006) as evidenced by Coleman et al (Protein Expression and Purification, 32:246-251, 2003) and Guyre et al (Cancer Immunol Immunother, 45:146-148, 1997).

Claims 1-3 and 7 are drawn to a targeting moiety comprising a conjugate of an "antibody" specific for a cell marker on targeted cells linked to the ligand-binding region of interleukin-4 receptor  $\alpha$  (IL-4R $\alpha$ ). Claims 20 and 21 are drawn to a composition comprising such a targeting moiety and a pharmaceutically acceptable carrier.

As explained in the above rejection, the claims are broadly but reasonably interpreted to read on a fusion protein comprising the covalent conjugate of an Fc fragment of an antibody and the ligand-binding portion of IL-4R $\alpha$ .

Seipelt et al teach a fusion protein comprising the ligand-binding extracellular domain of IL-4R  $\alpha$  linked to an Fc antibody fragment from human IgG (see entire document, e.g., abstract and page 535, left column). Furthermore, Seipelt et al teach said fusion protein in various experiments (e.g., Figure 2), so Seipelt et al inherently teach a composition comprising the fusion protein in an aqueous solution that comprises water.

Absent a showing of any difference, the disclosed aqueous solution comprising water (i.e., a pharmaceutically acceptable carrier) is the same as the compositions to which claims 20 or 21 are directed.

Thus Seipelt et al teach a targeting moiety comprising IL-4R  $\alpha$  and an Fc fragment that would specifically target CD64 on monocyte, macrophage and dendritic cells.

Therefore, Seipelt et al anticipate these claims.



14. Claims 1-3, 7, 20, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Enssle et al (US Patent 6,210,661, of record) as evidenced by Coleman et al (Protein Expression and Purification, 32:246-251, 2003), Guyre et al (Cancer Immunol Immunother, 45:146-148, 1997) and Seipelt et al (Biochem Biophys Res Comm, 239:534-542, 1997, IDS filed 9/25/2006).

Claims 1-3 and 7 are drawn to a targeting moiety comprising a conjugate of an "antibody" specific for a cell marker on targeted cells linked to the ligand-binding region of interleukin-4 receptor  $\alpha$  (IL-4R $\alpha$ ). Claims 20 and 21 are drawn to a composition comprising such a targeting moiety and a pharmaceutically acceptable carrier.

As explained in the above rejection, the claims are broadly but reasonably interpreted to read on a fusion protein comprising the covalent conjugate of an Fc fragment of an antibody and the ligand-binding portion of IL-4R $\alpha$ .

Enssle et al teach a fusion protein comprising the ligand-binding extracellular domain of IL-4R linked to an Fc antibody fragment (see entire document, e.g., abstract and columns 2 and 3). Furthermore, Enssle et al teach said fusion protein in compositions for treating diseases (e.g., column 2), so Enssle et al inherently teach a composition comprising the fusion protein and a pharmaceutically acceptable carrier.

As evidenced by Seipelt et al (Biochem Biophys Res Comm, 239:534-542, 1997, IDS filed 9/25/2006) the extracellular domain of IL-4 receptor is also known as IL-4R $\alpha$  (see entire document, e.g., 534, right column).

Thus Enssle et al teach a targeting moiety comprising IL-4R  $\alpha$  and an Fc fragment that specifically targets the cell marker CD64 on the surface of targeted monocyte, macrophage and dendritic cells.

Therefore, Enssle et al anticipate these claims.

***Claim Rejections - 102/103***

15. Claims 1-3, 7, 20, and 21 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Willson et al (WO 97/15663, 1997, IDS filed 9/25/2006).

Claims 1-3 and 7 are drawn to a targeting moiety comprising a conjugate of an "antibody" specific for a cell marker on targeted cells linked to the ligand-binding region of interleukin-4 receptor  $\alpha$  (IL-4R $\alpha$ ). Claims 20 and 21 are drawn to a composition comprising such a targeting moiety and a pharmaceutically acceptable carrier.

Willson et al teach fusion proteins comprising a polypeptide designated NR4 and immunoglobulins that allow targeting of NR4 to particular cells (See entire document, e.g., page 7, lines 15-21, page 10, lines 6-21 and page 11, lines 1-13). Furthermore, on page 6, Willson et al teach that NR4 polypeptides include a ligand-binding polypeptide that comprises an amino acid sequence derived from IL-4 receptor  $\alpha$ . Finally, Willson et al teach said fusion proteins in sterile aqueous solutions (e.g., page 19, lines 7-21) comprising pharmaceutically acceptable carriers and that such carriers include, for example, water.

While Willson et al do not expressly teach that the immunoglobulin genus includes antibodies, one of skill in the art would immediately recognize that the immunoglobulin genus includes antibodies, and therefore Willson et al anticipate these claims.

However, strictly in the alternative, if the immunoglobulin genus does not anticipate the antibody species, it would have been *prima facie* obvious to create fusion protein targeting moieties comprising IL-4 receptor  $\alpha$  and an antibody to target cells given the above teachings of Willson et al and the common art-recognized definition of an immunoglobulin. As evidenced by (Elgert et al. Immunology: Understanding the Immune System, 1996, page 59) immunoglobulins are defined, "as a family of globular proteins that comprise antibody molecules and molecules having patterns of molecular structure (antigenic determinants) in common with antibodies.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success at the time the invention to made to create fusion

protein targeting moieties comprising IL-4 receptor  $\alpha$  and an antibody as one of skill in the art would immediately recognize that antibodies are immunoglobulins that can specifically target cells and therefore could target IL-4 receptor  $\alpha$  to cells in a fusion protein comprising IL-4 receptor  $\alpha$  and an antibody specific for the targeted cells. Thus, there would be an advantage and a reasonable expectation of success in making fusion protein targeting moieties comprising IL-4 receptor  $\alpha$  and an antibody.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Claim Rejections - 35 USC § 103***

16. Claims 1, 6, 11 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willson et al (WO 97/15663, 1997, of record), in view of Hu et al (Cancer Research, 56:4998-5004, 1996, of record), Fritzberg et al (US patent 5,976,535) and Schwarz et al (Cancer Research, 55:3692-3696, 1995), as evidenced Rolling et al (FEBS Letters 393:53-56, 1996).

Claims 1, 6, 11 and 37 are drawn to a targeting moiety comprising a conjugate of an antibody specific for HLA-DR linked to the ligand-binding region of interleukin-4 receptor  $\alpha$  (IL-4R  $\alpha$ ).

As evidenced by Rolling et al (FEBS Letters 393:53-56, 1996), the IL4R $\alpha$  subunit is the same as the IL13R $\alpha$  subunit.

Willson et al teach what is set forth in the above 102/103 rejection.

However, Willson et al do not explicitly teach an antibody specific for HLA-DR to target particular target cells.

As evidenced by Rolling et al (FEBS Letters 393:53-56, 1996), this deficiency is made up for in the teachings of Hu et al, Fritzberg et al and Schwarz et al.

Hu et al teach a targeting moiety comprising a fusion protein of the Lym-1<sup>2</sup> antibody linked to interleukin-2 that targets interleukin-2 to lymphoma tumor cells (see entire document, e.g., page 4999, left column and page 5003, right column). Hu et al also teach that the Lym-1 antibody and the Lym-1/IL-2 fusion protein are cytotoxic to the lymphoma tumor cells (e.g., Figure 4). Fritzberg et al teach antibody targeting moieties comprising antibodies specific for a target cell conjugated to one member of a ligand/anti-ligand pair, such as streptavidin-biotin, for pre-targeting tumors with anti-tumor active agents, such as interleukin-4. (See entire document, e.g., columns 1, 3 and 4). Finally, Schwarz et al teach that interleukin 4 reduces tumor burden in a mouse xenograft model for lymphoma (see entire document, e.g., page 3693, right column and Figure 1).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to make a fusion protein targeting moiety comprising a conjugate of an antibody specific for HLA-DR linked to the ligand-binding region of interleukin-4 receptor  $\alpha$  (IL-4R  $\alpha$ ).

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success at the time the invention to made to make a fusion protein targeting moiety comprising a conjugate of an antibody specific for HLA-DR linked to the ligand-binding region of interleukin-4 receptor  $\alpha$  (IL-4R  $\alpha$ ) (i.e., the ligand binding region of IL-13R $\alpha$ ) because Willson et al and Hu et al teach fusion proteins comprising interleukin-4 receptor  $\alpha$  or an antibody specific for HLA-DR, respectively. Additionally, Hu et al and Schwarz et al teach that HLA-DR antibodies and IL-4, respectively, can inhibit the growth of and/or kill lymphoma tumor cells. Finally, Fritzberg et al teach that pretargeting an anti-tumor agent to a tumor by using an antibody specific for a tumor linked to an anti-ligand results in improved targeting of the tumor and less exposure of the recipient's non-target tissues to the active agent (e.g., column 1). In this case, creating a fusion protein targeting moiety comprising a conjugate of an antibody specific for HLA-DR linked to the ligand-binding region of

---

<sup>2</sup> See page 17, line 9, of the specification that discloses the Lym-1 antibody is directed against an HLA-

Art Unit: 1643

interleukin-4 receptor  $\alpha$  (IL-4R  $\alpha$ ) (i.e. a anti-ligand for IL-4) provides the further advantage over the pretargeting conjugates of Fritzberg which would require conjugating biotin to IL-4 because an anti-HLA-DR/IL-4R  $\alpha$  conjugate would directly bind IL-4. Thus, there would be an advantage and a reasonable expectation of success in making a fusion protein targeting moiety comprising a conjugate of an antibody specific for HLA-DR linked to the ligand-binding region of interleukin-4 receptor  $\alpha$  (IL-4R  $\alpha$ ), in view of Willson et al, Hu et al, Fritzberg et al and Schwarz et al.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

### ***Double Patenting***

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1643

18. Claims 1-3, 7, 20, and 21 are rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of US Patent No. 6,703,488 as evidenced by Rolling et al (FEBS Letters 393:53-56, 1996). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

Claims 1-3 and 7 are drawn to a targeting moiety comprising a conjugate of an antibody specific for a cell marker on targeted cells linked to the ligand-binding region of interleukin-4 receptor  $\alpha$  (IL-4R $\alpha$ ). Claims 20 and 21 are drawn to a composition comprising such a targeting moiety and a pharmaceutically acceptable carrier.

As evidenced by Rolling et al (FEBS Letters 393:53-56, 1996), the IL4R $\alpha$  subunit is identical to the IL13R $\alpha$  subunit (e.g., page 53, left column).

Claims 1-13 of US Patent 6,703,488 are drawn to a fusion protein targeting moiety comprising a conjugate of an antibody specific for carcinoembryonic antigen linked to the ligand-binding region of interleukin-13 receptor  $\alpha$  (IL-13R  $\alpha$ ), compositions comprising said fusion protein and methods of treating cancer comprising administering said fusion protein.

An antibody specific for carcinoembryonic antigen is a species of the genus of antibodies specific for a cell marker specific to a targeted cell.

Accordingly, the claimed inventions are so substantially similar that for the most part, the claimed subject matter of the copending application anticipates the claimed subject matter of the instant application and any minor differences in the subject matter claimed in the instant application would be seen as an obvious variation of the subject matter claimed in the copending application.

### ***Conclusion***

19. No claim is allowed.


Art Unit: 1643

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached on Monday through Friday 7:00 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully,  
Brad Duffy  
571-272-9935

  
STEPHEN RAWLINGS  
PRIMARY EXAMINER  
ART. UNIT 1643